REMARKS

Claim 24 remains in the application. Applicant has cancelled claims 25-36 without prejudice.

Applicants wish to express their appreciation for the courtesies extended applicants representatives, Dr. Kenneth I. Kohn and Laura Dellal, during a personal interview conducted on October 30, 2008. During the interview it was agreed that applicant would cancel claims 25 and 26 without prejudice and that claim 24 was ??? the presently uncovered prior art.

The pending claim was rejected under 35 U.S.C. §103(a) as being unpatentable over the reference to Masihi. The Office Action holds that the pending claims are directed to a method of treating or preventing an infection by administering a composition comprising an adjuvant in an effective amount of a protected IMP compound. More specifically, the pending claim is directed to a method of treating influenza, as set forth in claim 24 respectively. The claim includes the steps of administering an effective amount of a pharmaceutical composition comprising the protected IMP compound, detecting a T-cell response, and treating the influenza. In other words, in addition to the administrating step set forth in the Office Action, the claims further includes the steps of detecting a T-cell response and treating the influenza. Applicants' have cancelled composition claims, thereby rendering moot any argument with regard to composition structure characterizing the claims and have cancelled the additional previously set forth method claims in order to narrow the scope of the issues presently pending.

It is undisputed that Masihi teaches that the immune system can be manipulated either specifically by vaccination or non-specifically by immuno-modulation as set forth on pages 181-182, as cited in the Office Action. This generally is the crux of the Masihi article. Masihi discloses that this is critical since the focus of the medical community prior to the Masihi publication was overtly focused on a targeting microbial pathogens and ignoring strategies toward enhancing host immunity. Masihi recognized a problem due to

increased drug resistance and multi-drug resistance leaving experts concerned about a post-antibiotic era. Accordingly, Masihi reviewed a "diverse array of natural, synthetic, and recombinant immuno-modulators" in his article, disclosing how each one specifically potentiated or stimulated host defense mechanisms.

More specifically, the Masihi disclosure discussed immuno-modulators as a general category, focusing on non-specific stimulation of the immune system. The Masihi review focused on "immuno-stimulatory non-antibiotic agents capable of enhancing host defense mechanisms" and "augmentation of the anti-infectious immunity by the cells of the immune system" (page 181, col. 2). On page 184 of the Masihi article, in the paragraph bridging columns 1 and 2, Masihi discusses methyl inosine monophosphate (MIMP) as "an interesting thymomimetic immuno-modulator capable of inducing the expression of T-lymphosite differentiation markers in human prothymocytes." Specifically, the Masihi article discloses that MIMP has been shown to enhance mytogen induced proliferation of lymphosites, augment IgM plaque-forming cells, induce delayed type hypersensitivity, and normalize an impaired mouse response to IL-2. With specific regard to MIMP, the Masihi patent does not disclose or suggest the specifically claimed limitations of independent claims 24-26; that being the administration of the protected IMP compound, detecting a T-cell response, and treating either influenza, HIV infection, and treating or preventing an infection. Applicants are well aware of Masihi's disclosure as Masihi for this section of his article is quoting one of the present inventor's article, published in 1992. It must be undisputed that at that time, absent an antibiotic, there was no other treatment known or contemplated for the treatment of flu and there was absolutely no treatment known or contemplated for the treatment of HIV infection. Hence, Masihi is merely quoting the present inventors own article noting interesting cellular responses produced by MIMP, but not at all knowing or anticipating or even hypothesizing the presently claimed invention.

Referring to paragraph 6 of the Office Action in which a counterargument is presented with regard to the previously set forth arguments, the first argument presented in the Office Action is that a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

patentably distinguish the claimed invention from the prior art. This refers to a structural difference in composition. Applicant has cancelled the previously pending composition claims rendering this basis for rejection moot. On page 5 of the Office Action, the Office Action sets forth a second basis for rebutting Applicants' previously set forth argument based on the argument that inherently possessed function or property by things in the prior art does not cause the claim drawn to those things to distinguish over the prior art. Again, this relates to the previously claimed composition which has been cancelled and therefore withdrawn from consideration without prejudice. The presently pending method claim includes method steps that are not at all contemplated or disclosed in the reference, as the reference cites one of the present inventor's own article of which he is intimately aware and knowledgeable of. Again, at best, the Masihi article discloses that MIMP, specifically, is an interesting thymomematic immuno-modulator that induces various cellular responses, but absolutely, there is no disclosure that such a compound or a protected IMP compound in general, can successfully treat influenza, and that one can detect a T-cell response in such treatments. There is absolutely and undisputably no such disclosure in the Masihi reference. Such a discovery therefore must be considered invention over the prior art especially since such a discovery is such a tremendous clinical leap in medicine.

If the Masihi article is considered as a basis for a *prima facia* obviousness-type rejection which is rebuttable by factual evidence of unexpected results as a matter of law, then Applicant directs attention to the various examples set forth in the presently pending application which clearly demonstrate the unexpected results of the present invention as a treatment for, and as a prophylaxis for, influenza. Although all the examples in the application are relevant, specific attention is drawn to examples 3, 5 and 6 wherein immune response is clearly demonstrated in example 3 and pre-exposure protection is clearly shown to be conferred in examples 5 and 6. Amazingly, Figures 7 and 8, for the first time, show unequivocal enhancement of T-cell response to HIV vaccine. Hence, the present application provides factual evidence of examples of undeniably unexpected results as such results were previously not shown in any art and certainly were not disclosed in the Masihi article or any article quoted by Masihi. Hence, it is respectfully

submitted, that as a matter of law, Applicants present factual evidence that would rebut a *prima facia* obviousness rejection if such was held based on the Masihi reference.

In view of the above, it is respectfully submitted that the presently pending independent claims be allowed.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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I hereby certify that this correspondence is being electronically filed with the United States Patent & Trademark Office on the above date.

Terry Horst